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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,171	02/04/2002	Sally Mossman	014058-013300US	8073

20350 7590 02/24/2006

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/068,171

Applicant(s)

MOSSMAN ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 91,94,96-102,105-114 and 117-126 is/are pending in the application.
- 4a) Of the above claim(s) 96-98,100,108-110,112,113,120 and 122-126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 91,94,99,101,102,105-107,111,114,117-119 and 121 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2005 has been entered. Claims 91, 94, 96-102, 105-114, 117-126 are pending, claims 96-98, 100, 108-110, 112-113, 120, 122-126 are withdrawn from further consideration as drawn to nonelected species.

The claims have been examined insofar as they read on the elected invention and species.

### *Double Patenting Rejections*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 91, 94, 99, 101, 102, 105, 111, 114, 117, 121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-25, 29-30 of copending Application No. 10/177,115. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims herein are generic to those claims in '115. '115 claims a method of enhancing the immune response with QS 21 and, RC-529, a compound with the scope of the compounds herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections 35 U.S.C. 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 91, 92, 94, 99, 101, 102, 105, 111, 114, 117, 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), and in further view of applicants' own admission.

3. Johnson et al. teach that aminoalkyl glucosamine phosphates, including the particular elected AGP herein, are known as adjuvant, and immunoeffectors. Johnson further teaches that the adjuvants composition may be in various forms including oil-in-water or water-in-oil emulsions, aqueous composition, liposome, etc; vaccine composition comprising the AGP and antigen. Johnson et al. also teach a method of using the AGP for enhancing the immune response

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of an animal. See, particularly, the abstract, columns 2-5, example 20 in column 42, and the claims.

4. Johnson et al do not teach expressly the employment of a combination of AGP and Quil A for enhancing the immune response.

5. However, Kensil et al. teaches that Quil A, including QS 21, is known to be useful as immune adjuvant, which is useful for stimulating immune response, particularly co-administered with antigen. The adjuvant may be administered individually or admixed with other adjuvants to achieve the enhancements of the immune response to antigen, including those of tuberculosis. See, particularly, the abstract, column 6, line 54 to column 7, lines 40, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising the two adjuvants herein, i.e., quil A and the particular AGP herein, and optionally further comprising antigen, such as those for tuberculosis.

A person of ordinary skill in the art would have been motivated to composition comprising the two adjuvants herein, i.e., Quil A and the particular AGP herein, and optionally further comprising antigen, such as those for tuberculosis because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus , the claimed invention which is a combination of two known adjuvants sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. As to the particularly amount of each active ingredients herein, note, the optimization of a result effective parameter, e.g., amounts of

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the active ingredients in a pharmaceutical composition, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. With respect to the particular antigen herein, note applicants acknowledged that such antigen was known in the art. See the example 1 herein at page 74. Using a known antigen properly is within the skill of artisan.

6. Claims 106, 107, 118, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), and in further view of applicants' own admission as set forth above, and in further view of De Vrier et al.

7. Johnson et al. and Kensil et al. as a whole do not teach expressly the employment of phospholipid in the immunogenic composition employed herein.

8. However, De Vries et al. disclosed that for immunogenic composition with antigens, surfactants, such as phospholipids, are known to be useful, particularly with saponin. See, particularly, the abstract, col. 3, lines line 9-62, and the claims.

9.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to incorporate surfactants, such as phospholipids in the aqueous immunogenic composition.

A person of ordinary skill in the art would have been motivated to incorporate surfactants, such as phospholipids in the aqueous immunogenic composition because surfactants, such as phospholipids, are known to be useful in such composition for stabilizing the antigen containing composition.

10. Claims 91, 92, 94-95, 99, 101, 102, 105, 111, 114, 117, 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al.

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(US 5,057,540), and in further view of applicants' own admission, for reasons discussed above, and in further view of Johnson (US 2001/0053363, IDS) or Mossman et al. (WO 02/03961, IDS).

11. Johnson and Mossman et al. provide further motivation to combine the two adjuvants, AGP and Quil A. Particularly, Mossman et al. teach that AGP and Quil A are useful together and disclose a composition comprising both AGP and Quil A, See, particularly, claims 32 and 42. The AGP disclosed by Mossman including those herein employed see the figures. Johnson also discloses that saponin and AGP adjuvants are useful together and may produce synergistic effect. See, particularly example 7 at pages 28-29. Therefore, one of ordinary skill in the art, would have been further motivated to combine the two adjuvants as herein claimed, since it have been shown that two adjuvants are useful together as have been expected, and may produce synergistic effect.

12. Claims 106, 107, 118, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), and in further view of applicants' own admission as set forth above, and in further view of De Vrier et al, for reasons set forth above, and in further view of Johnson (US 2001/0053363, IDS) or Mossman et al. (WO 02/03961, IDS).

13. Johnson and Mossman et al. provide further motivation to combine the two adjuvants, AGP and Quil A. Particularly, Mossman et al. teach that AGP and Quil A are useful together and disclose a composition comprising both AGP and Quil A, See, particularly, claims 32 and 42. The AGP disclosed by Mossman including those herein employed see the figures. Johnson also discloses that saponin and AGP adjuvants are useful together and may produce synergistic effect.

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See, particularly example 7 at pages 28-29. Therefore, one of ordinary skill in the art, would have been further motivated to combine the two adjuvants as herein claimed, since it have been shown that two adjuvants are useful together as have been expected, and may produce synergistic effect.

***Response to the Arguments***

14. Applicants' 132 declaration and the remarks submitted December 12, 2005 have been fully considered, but are not persuasive.

15. The declaration under 37 CFR 1.132 filed December 12, 2005 is insufficient to overcome the rejection of claim 91, 92, 94-95, 99, 101, 102, 105, 111, 114, 117, 121 based upon Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), as set forth in the last Office action because: a prima facie case of unexpected results commensurate in scope with the claimed invention has not been established. Particularly, the evidence presented are not significant and not convincing as to establish unexpected and/or synergistic effects. Absent evidence to the contrary, a synergistic effect of a combination of two agents is expected to be that of more than the adduct of the effects from the two individual agents. The data presented in the declaration, showing that most of the combinations merely have more or less of the adduct of the individual effects, lack probative force for unexpected results. Only the combination of RC-529 and QS 21 is distinct from the others as having synergistic effect. However, that subject matter is already covered by the allowed copending application 10/177,115.

16. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.



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17. Further, the evidences do not commensurate in scope with the claimed invention. Specifically the claimed invention cover all saponin, and the data only show one particular saponin, QS 21.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG  
PRIMARY EXAMINER

Shengjun Wang  
Primary Examiner  
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